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Date: November 1, 2010  
 To: Health Care Providers  
 From: Nebraska Public Health Laboratory

We are writing to share information on the reporting of laboratory test results for chlamydia (CT) and gonorrhea (GC). Effective November 1, 2010, the NPHL will be adding “indeterminate” as a new test result category (see Table 1) for reasons that are summarized in the discussion below. In addition, we have reviewed our records for the past two years and identified those cases that would have been reported as “indeterminate” if this approach had been in place. The clinic and provider name with their respective clients are appended. Based on the clinical circumstances and recommendations by the CDC, medical providers may choose to have individuals retested. You are welcome to contact Dr. Hinrichs (402)-559-7255 for any related questions.

**Table 1: New CT/GC result reporting, effective November 1, 2010.**

Initial Test Score	Repeat Test Score	Interpretation
≥ 10,000	N/A	POSITIVE
Gray zone <sup>a</sup>	≥ 10,000	POSITIVE
Gray zone	2000 – 9999	LOW POSITIVE <sup>b</sup>
Gray zone	< 2000	INDETERMINATE <sup>c,d</sup>
< 2000	N/A	NEGATIVE

<sup>a</sup> Gray zone is a test score of ≥ 2000 and < 10,000.

<sup>b</sup> The positive predictive value (PPV) for these results is > 90%.

<sup>c</sup> Up to 10% of patients with these results may be true positives, and 90% of these cases may be negative. CDC unpublished data

<sup>d</sup> Submit new specimen if indicated, or treat patient based on clinical judgment.

**Background and Discussion.**

Implementation of this new reporting format is in response to a recent nationally distributed letter from the Centers for Disease Control and Prevention (CDC). Subsequently, a clarification of the letter was released that addressed a variety of concerns. These letters and statements (available for review online at: NPHL.org) provided recommendations on testing procedures and reporting of results that may be generated at the lowest level of accuracy of the assay.

Our laboratories have been utilizing the BD ProbeTec™ ET CT/GC Amplified DNA Assay employing molecular amplification technology since 2002. As with any test, the positive predictive value (PPV) is greatly influenced by the prevalence of disease in a population, and we found additional measures were needed to improve diagnostic accuracy in the low range of detection, referred to as the gray zone. Our laboratory followed CDC recommendations to perform repeat testing on samples at or near the lowest range of detection (the CDC MMWR on this topic is available on line at: <http://www.cdc.gov/std/treatment/default-2002.htm>). Table 2 below shows the original reporting format used by our laboratories. If the sample did not repeat it was reported as negative. If the sample repeated in the same range it was reported as positive with no further clarification.

**Table 2: Original CT/GC result reporting from 2002 test inception to August 26, 2010<sup>a</sup>.**

Initial Test Score	Repeat Test Score	Interpretation
≥ 12,000	N/A	POSITIVE
Gray zone <sup>b</sup>	≥ 2000	POSITIVE <sup>c</sup>
Gray zone	< 2000	NEGATIVE <sup>d</sup>
< 2000	N/A	NEGATIVE

<sup>a</sup> Following an in-house validation that demonstrated excellent performance values for this assay.

<sup>b</sup> Gray zone is a test score of ≥ 2000 and < 12,000.

<sup>c</sup> Data indicate that the PPV for these results is > 90%.

<sup>d</sup> Data indicate that 10% of these results will be false negative (CDC unpublished data)

After we received the first CDC letter recommending that tests with gray zone results not repeating in the gray zone be reported as “low positive”, we began reporting our test results on August 26, as shown in table 3. This approach was intended to increase the number of people treated for infection and was based in part on a recent lookback study for chlamydia by CDC. That study found approximately 10% of patients reported as negative on the basis of discordant repeat test results were later found to be positive, although some of these individuals may have been infected following the original testing. The concern with reporting all gray zone results as positive is that it may result in 9 false positive reports out of the 10 tested individuals and require subsequent public health investigation to identify and treat sexual partners unnecessarily.

**Table 3: CT/GC result reporting from August 26, 2010 – November 1, 2010<sup>a</sup>.**

Initial Test Score	Repeat Test Score	Interpretation
≥ 10,000	N/A	POSITIVE
Gray zone <sup>b</sup>	N/A	LOW POSITIVE <sup>c</sup>
< 2000	N/A	NEGATIVE

<sup>a</sup> Based on CDC recommendations received August 16, 2010; however, after further discussions and clarification of CDC intent, we will begin reporting results as in Table 1 above.

<sup>b</sup> Gray zone is a test score of ≥ 2000 and < 10,000.

<sup>c</sup> Clinical judgment should be used in management of these patients.

Following further discussion and clarification of the CDC intent, an alternative approach was considered to be more appropriate as shown in Table 1. Beginning November 1, samples with test results in the gray zone that do not repeat will be reported as “indeterminate”. Further, we will suggest the collection of an additional new specimen if clinically indicated in the judgment of the provider. Samples that repeat positive in the gray zone will be reported as “low positive.”

If clients from your clinic may have been impacted by the issues in this letter, their names and the available provider names are appended below. If there are any errors in the records or you have questions about these cases, you are encouraged to call NPHL client services at (402)-559-2440.